

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD.	)	
KYORIN PHARMACEUTICAL CO., LTD.	)	
ALLERGAN, INC.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 12-cv-0159-SLR
	)	
APOTEX, INC. and APOTEX CORP.	)	
	)	
Defendants.	)	

**DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex") for their Answer, Affirmative Defenses and Counterclaim to Plaintiffs' Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd., and Allergan, Inc. (collectively "Plaintiffs" or "Senju") Complaint state as follows:

**Nature of the Action**

1. This is an action for infringement of United States Patent No. 6,333,045 ("the '045 Patent"), the claims set forth on the '045 Patent reexamination certificate, and United States Patent No. 5,880,283 ("the '283 Patent") under 35 U.S.C. §271(e)(2).

**ANSWER:** Defendants admit that this action purports to be one for infringement of United States Patent Nos. 6,333,045 ("the '045 patent"), including the claims set forth in the '045 patent reexamination certificate, and 5,880,283 (the '283 patent").

**The Parties**

2. Plaintiff Senju is a corporation organized under the laws of Japan having a place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

**ANSWER:** Admitted upon information and belief.

3. Plaintiff Kyorin is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311 Japan.

**ANSWER:** Admitted upon information and belief.

4. Plaintiff Allergan is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

**ANSWER:** Admitted upon information and belief.

5. On information and belief, defendant Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

**ANSWER:** Admitted.

6. On information and belief, defendant Apotex Corp. offers for sale and sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

**ANSWER:** Apotex admits that Apotex Corp. offers for sale and sells drug products in the United States, including this judicial district, manufactured and supplied by Apotex, Inc. All other allegations of paragraph 6 are denied.

7. On information and belief, defendant Apotex, Inc. is a corporation organized under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

**ANSWER:** Admitted.

8. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

**ANSWER:** Apotex admits that Apotex, Inc. manufactures numerous drug products for sale

and use in the United States including this judicial district, but denies all other allegations set forth in paragraph 8.

9. On information and belief, Apotex, Inc. is formulating and/or plans to formulate gatifloxacin ophthalmic solution to be marketed and sold in the United States by Apotex Corp. Plaintiffs reserve the right to amend the complaint to substitute a different party for Apotex Inc. and/or Apotex Corp. if, through discovery, Plaintiffs discover that a company other than Apotex, Inc. and/or Apotex Corp. is formulating and/or marketing and/or selling gatifloxacin ophthalmic solution.

**ANSWER:** Apotex denies the allegations set forth in paragraph 9. Additionally, Plaintiffs attempt to reserve rights to amend its complaint in paragraph 9 is futile, amendment of the complaint is governed by the Federal Rules of Civil Procedure, the Local Rules of this Court and any scheduling order that this Court enters in this case.

10. On information and belief, the acts of Apotex Corp. complained of herein were done with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of Apotex, Inc.

**ANSWER:** The averments of paragraph 10 are sufficiently vague and ambiguous that Apotex denies information or knowledge sufficient to form a belief as to those averments and therefore denies and demands strict proof thereof.

#### **Jurisdiction and Venue**

11. This action arises under 35 U.S.C. Section 1, *et seq.* This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Admitted.

12. This Court has personal jurisdiction over Apotex because of its continuous and

systematic contacts with Delaware. On information and belief, Apotex directly or indirectly purposefully sells, markets, distributes, and manufactures, goods for sale in the United States and Delaware; derives substantial revenue from things used or consumed in Delaware, regularly does and solicits business in Delaware; has filed counterclaims in this Court in other actions purposefully availing itself of the rights and benefits of this Court; and has admitted and/or consented to jurisdiction in this Court on numerous occasions, including with respect to another litigation involving gatifloxacin ophthalmic solutions versus the same Plaintiffs, *e.g.*, *Senju Pharmaceuticals Co., Ltd et al. v. Apotex Inc. et al.*, 07-779 (D. Del.).

**ANSWER:** Apotex admits that Apotex Corp. and Apotex, Inc. consent to jurisdiction in this Court for this action. Apotex further admits that it has consented to the jurisdiction in this Court in another litigation involving gatifloxacin ophthalmic solutions versus the same Plaintiffs, *e.g.*, *Senju Pharmaceuticals Co., Ltd et al. v. Apotex Inc. et al.*, 07-779 (D. Del.). Apotex denies the remaining allegations set forth in paragraph 12.

13. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** Admitted.

### **Background**

14. The '045 Patent, entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin," issued on December 25, 2001. A copy of the '045 Patent, reexamination certificate, and certificate of correction is attached to this complaint as Exhibit A.

**ANSWER:** Apotex admits that what purports to be a copy of the '045 patent is attached to the Complaint as Exhibit A, which is entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin" and lists an issue date of December 25, 2001. Apotex denies any

remaining allegations contained in paragraph 14.

15. Senju and Kyorin jointly own the entire right and interest in the '045 Patent.

**ANSWER:** Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 15 and therefore denies them.

16. Allergan is the exclusive licensee of the '045 Patent for ophthalmic uses.

**ANSWER:** Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 16 and therefore denies them.

17. The '283 Patent, entitled "8-Alkoxyquinolonecarboxylic Acid Hydrate With Excellent Stability And Process For Producing The Same," issued on March 9, 1999. Claim 1 of the '283 Patent claims gatifloxacin sesquihydrate. A copy of the '283 Patent is attached to this complaint as Exhibit B.

**ANSWER:** Apotex admits that what purports to be a copy of the '283 patent is attached to the Complaint as Exhibit B, which is entitled "8-Alkoxyquinolonecarboxylic Acid Hydrate With Excellent Stability And Process For Producing The Same," and lists an issue date of March 9, 1999. Apotex denies any remaining allegations contained in paragraph 17.

18. Kyorin owns the entire right and interest in the '283 Patent.

**ANSWER:** Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 18 and therefore denies them.

19. Allergan is the exclusive licensee of the '283 Patent for ophthalmic uses.

**ANSWER:** Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 19 and therefore denies them.

20. Each claim of the '045 Patent, the '045 Patent reexamination certificate, and the '283 Patent has a statutory presumption of validity that exists at all stages of a

proceeding.

**ANSWER:** The allegations of paragraph 20 are conclusions of law to which no response or pleading is required, and therefore they are denied.

21. The '045 Patent was previously asserted by Plaintiffs against Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.).

**ANSWER:** Admitted.

22. On June 21, 2010, the United States District Court for the District of Delaware entered judgment that Claims 1-3 and 6-9 of the '045 Patent were invalid as obvious.

**ANSWER:** Admitted.

23. On November 3, 2010, the United States District Court for the District of Delaware reopened the record to take additional testimony with respect to claim 7 of the '045 Patent.

**ANSWER:** Apotex admits that in an Order dated November 3, 2010, the United States District Court for the District of Delaware opened the record of Case No. 07-779-SLR for the parties to present additional evidence on the narrow issue of "the relationship between precipitation and solubility." Apotex denies all remaining allegations contained in paragraph 23.

24. On December 20, 2011, the United States District Court for the District of Delaware entered judgment that Claim 7 of the '045 patent was invalid as obvious.

**ANSWER:** Admitted.

25. Plaintiffs are appealing the district court's judgment with respect to Claim 7 of the '045 Patent from the United States District Court for the District of Delaware to the United States Court of Appeals for the Federal Circuit.

**ANSWER:** Apotex admits that on January 18, 2012, Plaintiffs filed a Notice of Appeal to the Federal Circuit appealing the district court's judgment with respect to Claim 7 of the '045

Patent from the United States District Court for the District of Delaware. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 25 and therefore denies them.

26. On February 25, 2011, Senju and Kyorin filed a request for reexamination of Claims 1-3, 6, 8 and 9 of the '045 Patent with the United States Patent and Trademark Office. Plaintiffs did not request reexamination of Claims 4, 5 and 7. The request was granted on April 28, 2011, and assigned Reexamination Application Control No. 90/011509.

**ANSWER:** Admitted on information and belief.

27. During the prosecution of Reexamination Application Control No. 90/011509, Plaintiffs submitted, for consideration by the United States Patent and Trademark Office, the prior art, other evidence, and arguments relied upon by the Court and Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.) and the Court's decision in that case. Plaintiffs further canceled claims 1-3 and 8-11, amended claim 6 and added claims 12-16.

**ANSWER:** Apotex admits that Plaintiffs canceled claims 1-3 and 8-11 of the '045 patent during the prosecution of Reexamination Application Control No. 90/011509. Apotex further admits that Plaintiffs amended claim 6 and added claim 12-16 of the '045 patent during the prosecution of Reexamination Application Control No. 90/011509. Apotex denies the remaining averments set forth in paragraph 27.

28. On October 25, 2011, the United States Patent and Trademark Office issued a reexamination certificate for the '045 Patent, canceling claims 1-3 and 8-11, and issuing amended claim 6 and new claims 12-16 as patentable over the opinion, prior art, other evidence, and arguments from *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.).

The United States Patent and Trademark Office informed Plaintiffs of the publication of the '045 patent reexamination certificate on October 27, 2011.

**ANSWER:** Apotex admits that on October 25, 2011, the United States Patent and Trademark Office issued a reexamination certificate for the '045 Patent, canceling claims 1-3 and 8-11, and issuing amended claim 6 and new claims 12-16. Apotex denies that amended claim 6 and new claims 12-16 are as patentable over the opinion, prior art, other evidence, and arguments from *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.) or that the United States Patent Office was supplied with the complete prior art, evidence and arguments from said action. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 28 and therefore denies them.

29. Allergan is the holder of approved New Drug Application ("NDA") No. 22-548 that covers Zymaxid®, a 0.5% ophthalmic solution of gatifloxacin.

**ANSWER:** Admitted on information and belief.

30. In conjunction with NDA No. 22-548, Allergan has listed the '045 Patent, the '283 patent and other patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") maintained by the U.S. Food and Drug and Administration ("FDA"). Allergan also informed FDA of the issuance of the '045 Patent reexamination certificate. Listing patents in the Orange Book obligates drug companies seeking approval to market a generic version of listed drug before the expiration of a listed patent to provide notice to the owner of the listed patent(s) and to the NDA holder with certain exceptions which do not apply to this case.

**ANSWER:** Apotex admits that the FDA lists Allergan as the holder of approved New Drug Application ("NDA") No. 22-548 on its website. Apotex further admits on information and



belief that Allergan has listed the '045 and '283 patents in the Orange Book. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 30 and therefore denies them.

31. On information and belief, Apotex filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% with a Paragraph IV certification.

**ANSWER:** Apotex admits that it filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5%, which contains a Paragraph IV certification. Apotex denies all remaining allegations set forth in paragraph 23.

32. Upon information and belief, ANDA No. 203523 refers to, and relies upon, Allergan's NDA No. 22-548 and contains data that, according to Defendants, demonstrates the bioequivalence of the Defendants' proposed ANDA product to Allergan's Zymaxid® which is the subject of NDA No. 22-548.

**ANSWER:** Apotex admits that NDA No. 22-548 is identified in ANDA No. 203523 as the reference listed drug. Apotex denies all remaining allegations set forth in paragraph 32.

33. In a letter dated January 13, 2012, Apotex advised Plaintiffs that it had filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% which is the subject of Allergan's NDA. Allergan received that letter on January 16, 2012.

**ANSWER:** Apotex admits that Apotex transmitted a letter dated January 13, 2012 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 30 and therefore denies them.

34. The January 13, 2012 letter purports to advise Plaintiffs pursuant to 21 U.S.C.

§355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that Apotex's ANDA No. 203523 had been filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.5% before the expiration of either the '045 Patent or U.S. Patent 5,880,283 (the '283 patent).

**ANSWER:** Apotex admits that Apotex transmitted a letter dated January 13, 2012 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied.

35. The January 13, 2012 letter does not state where the product of ANDA No. 203523 is to be manufactured and/or formulated.

**ANSWER:** Apotex admits that Apotex transmitted a letter dated January 13, 2012 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied.

36. Upon information and belief, Apotex manufactured and continues to manufacture, at least some, gatifloxacin sesquihydrate.

**ANSWER:** Apotex denies all allegations set forth in paragraph 36.

37. Upon information and belief, Apotex's gatifloxacin API contains at least some gatifloxacin sesquihydrate.

**ANSWER:** Apotex denies all allegations set forth in paragraph 37.

### **COUNT 1**

#### **Infringement of Claims 6-7, 12, and 14-16**

38. Paragraphs 1-38 are incorporated herein as set forth above.

**ANSWER:** Apotex repeats and reasserts its responses set forth in paragraphs 1-37 as if set

forth herein in full.

39. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.5% in the United States before the expiration of the '045 Patent is an act of infringement of Claim 7 of the '045 Patent and Claims 6, 12 and 14-16 set forth on the '045 Patent reexamination certificate under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** The averments of paragraph 39 set forth conclusions of law to which no response or pleading is required. To the extent that such averments require a response, those averments are denied.

40. Defendants are jointly and severally liable for infringement of those claims.

**ANSWER:** Apotex denies all allegations set forth in paragraph 40.

41. Apotex's participation in the submission of ANDA No. 203523 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Apotex denies all allegations set forth in paragraph 41.

42. Upon information and belief, Defendants were aware of the existence of the '045 Patent and the '045 Patent reexamination certificate and were aware that the filing of ANDA No. 203523 and certification with respect to the '045 Patent and the '045 Patent reexamination certificate constituted infringement. This is an exceptional case.

**ANSWER:** Apotex admits that it was aware of the '045 patent and reexamination certificate at the time that ANDA No. 203523 was filed. Apotex denies all remaining allegations set forth in paragraph 42.

**COUNT 2**

**Infringement of Claim 1 of the '283 Patent**

43. Paragraphs 1-43 are incorporated as set forth herein.

**ANSWER:** Apotex repeats and reasserts its responses set forth in paragraphs 1-43 as if set forth herein in full.

44. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution, 0.5% in the United States before the expiration of the '283 Patent was an act of infringement of Claim 1 under 35 U.S.C. 271(e)(2)(A) of the '283 Patent.

**ANSWER:** The averments of paragraph 44 set forth conclusions of law to which no response or pleading is required. To the extent that such averments require a response, those averments are denied.

45. Defendants are jointly and severally liable for infringement of the '283 Patent.

**ANSWER:** Apotex denies all allegations set forth in paragraph 45.

46. Apotex's participation in the submission of ANDA No. 203523 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '283 Patent under 35 U.S.C. §271(e)(2)(A).

**ANSWER:** Apotex denies all allegations set forth in paragraph 46.

47. Upon information and belief, Defendants were aware of the existence of the '283 Patent and were aware that the filing of ANDA No. 203523 and certification with respect to the '283 Patent constituted infringement of that patent. This is an exceptional case.

**ANSWER:** Apotex admits it was aware of the '283 patent at the time that ANDA No. 203523

was filed. Apotex denies all remaining allegations set forth in paragraph 47.

**PRAYER FOR RELIEF**

**ANSWER:** Apotex specifically denies that Plaintiffs are entitled to the general or specific relief requested against Apotex, or to any relief whatsoever, and prays for judgment in favor of Apotex dismissing this action with prejudice, and awarding Apotex its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Apotex, Inc. and Apotex Corp. (collectively "Apotex") aver and assert the following Affirmative Defenses to Plaintiffs', Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd. and Allergan, Inc.'s Complaint.

**FIRST AFFIRMATIVE DEFENSE  
(Noninfringement of U.S. Patent No. 6,333,045)**

The manufacture, use, sale, offer to sell or importation into the United States of Apotex's proposed gatifloxacin ophthalmic solution that is the subject matter of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 6,333,045 ("the '045 patent") either literally or under the doctrine of equivalents.

**SECOND AFFIRMATIVE DEFENSE  
(Invalidity of U.S. Patent No. 6,333,045)**

Upon information and belief, the claims of the '045 patent are invalid and/or unenforceable for failure to comply with one or more of the provisions of Title 35 of the United

States Code, including, but not limited to Sections 101, 102, 103 and/or 112, and/or 37 CFR § 1.56.

**THIRD AFFIRMATIVE DEFENSE**  
**(Noninfringement of U.S. Patent No. 5,880,283)**

The manufacture, use, sale, offer to sell or importation into the United States of Apotex's proposed gatifloxacin ophthalmic solution that is the subject matter of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 5,880,283 ("the '283 patent") either literally or under the doctrine of equivalents.

**FOURTH AFFIRMATIVE DEFENSE**  
**(Invalidity of U.S. Patent No. 5,880,283)**

Upon information and belief, the claims of the '283 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

**FIFTH AFFIRMATIVE DEFENSE**  
**(Unenforceability of U.S. Patent No. 6,333,045)**

For the reasons stated in Count V of Apotex's Counterclaims below, the '045 patent is unenforceable due to inequitable conduct committed during its reexamination with unclean hands including, without limitation, the failure of the applicants, inventors, and/or those involved in the reexamination, with intent to deceive the USPTO, to disclose prior art and information that was material to the reexamination of the '045 patent.

**SIXTH AFFIRMATIVE DEFENSE**  
**(Issue Preclusion)**

Plaintiffs have previously litigated, and lost, on the legal issue of invalidity of the claims of the '045 patent, and are thus barred by issue preclusion from relitigating the issue of invalidity

of the remaining claims of the '045 patent, which are substantially similar to the claims previously litigated and held invalid.

### **COUNTERCLAIMS**

1. Counterclaimant Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

2. Counterclaimant Apotex, Inc. is a corporation organized under the laws of Canada, and its principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Upon information and belief, Counterclaim Defendant Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized and existing under the laws of Japan having a place of business at 2-5-8, Hirano-Machi, Chuo-ku, Osaka 541-0046, Japan.

4. Upon information and belief, Counterclaim Defendant Kyorin Pharmaceutical Co., Ltd. ("Kyorin") is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311, Japan.

5. Upon information and belief, Counterclaim Defendant Allergan, Inc. ("Allergan") is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

6. As a consequence of Plaintiffs/Counterclaim Defendants' complaint against Apotex Corp. there is now an existing, continuing actual controversy between Senju, Kyorin and Allergan and Apotex Corp., regarding the alleged infringement, validity and enforceability of U.S. Patent Nos. 6,333,045, ("the '045 patent") and 5,880,283 ("the '283 patent").

7. This Court has jurisdiction over the subject matter of these counterclaims

pursuant to §§ 1331 and 1338 (a) of Title 28 of the U.S. Code because they involve substantial claims arising out of the United States Patent Act, 35 U.S.C. § 1, *et. seq.*

8. This Court may declare the rights and legal relation for the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271 (e)(5) of Title 35 of the U.S. Code because Apotex Corp.'s counterclaims present an actual controversy within the Court's jurisdiction that the patents asserted by Plaintiffs/Counterclaim Defendants against Defendant/Counterclaim Plaintiff, Apotex Corp. are not infringed and/or are invalid.

9. Venue for these counterclaims is proper within this District in which Plaintiffs/Counterclaim Defendants' Complaint is pending.

**COUNT I**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '045 PATENT**

10. The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '045 patent either literally or under the doctrine of equivalents.

**COUNT II**  
**DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '045 PATENT**

11. Upon information and belief, the claims of the '045 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

**COUNT III**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '283 PATENT**

12. The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of



ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '283 patent either literally or under the doctrine of equivalents.

**COUNT IV**  
**DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '283 PATENT**

13. Upon information and belief, the claims of the '283 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

**COUNT V**  
**DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '045 PATENT**

14. Counterclaimants Apotex, Inc. and Apotex Corp. (collectively "Apotex") incorporate by reference the allegations of paragraphs 1-13 of their Counterclaims, as though fully set forth herein.

15. The '045 patent and its claims are unenforceable due to inequitable conduct committed during its reexamination, as more fully set forth below.

16. Title 37 of the Code of Federal Regulations § 1.56 and the Manual for Patent Examining Procedure § 2000.01 *et seq.* impose a duty of candor and good faith on each individual associated with the filing and prosecution of a patent application before the United States Patent and Trademark Office ("USPTO"), including reexamination, which requires that he or she disclose to the USPTO all information that is material to the patentability of the application under examination. Breach of this duty of candor, good faith and honesty with an intent to deceive the USPTO constitutes inequitable conduct so as to render the affected patent(s) unenforceable.

17. Upon information and belief, the '045 patent is void, unenforceable and of no

legal effect by reason of inequitable conduct on the part of the inventors thereof and/or those acting on their behalf before the USPTO. Senju, Kyorin, the inventors and/or those acting on their behalf committed acts of inequitable conduct by failing to disclose information material to the reexamination of their respective applications and/or by submitting false or misleading information material to the reexamination of the applications. Specifically, Senju, Kyorin, the inventors and/or those acting on their behalf made affirmative misrepresentations and omitted material information in an attempt to distinguish the subject matter claimed in the '045 patent and reexamination certificate for that patent from that disclosed in the prior art. All such acts were committed with an intent to deceive the USPTO.

**Inequitable Conduct During Reexamination**

18. On February 25, 2011, Senju and Kyorin filed an *ex parte* request for the reexamination of claims 1-3, 6, 8, and 9 of the '045 patent with the United States Patent and Trademark Office ("USPTO") seeking to amend the claims. At the time of the reexamination request, these six claims were subject to a judgment ruling them invalid as obvious.

19. As part of the reexamination request, Senju and Kyorin filed the trial opinion, excerpts of the trial record, and certain expert reports that were favorable to their position on reexamination.

20. Senju and Kyorin did not file excerpts of the trial record and expert reports disclosing that Kyorin's researchers had been the first to make and test gatifloxacin ophthalmic formulations covered by the '045 patent claims, nor did they produce evidence which showed that the formulations as claimed by the '045 patent did not exhibit unexpected results, the existence of which could have supported patentability.

21. Senju and Kyorin also did not file the deposition testimony by their own expert

conceding that preparing the aqueous liquid compositions containing 0.3 w/v% gatifloxacin and 0.01 w/v% disodium edetate would have been obvious based on the well-known use of disodium edetate to prevent coloration of aqueous liquid drug formulations.

22. This withheld information was material to patentability and shows that the added reexamination claims of the '045 patent were invalid as a matter of law as obvious. Withheld information also shows that Senju and Kyorin made a material misrepresentation about the presence of a secondary consideration supporting obviousness—contemporaneous invention.

23. On information and belief, Senju and Kyorin withheld this material information with an intent to deceive the USPTO with respect to the patentability of the subject matter claimed in the '045 patent and reexamination certificate.

24. On information and belief, Senju and Kyorin withheld this invalidating and contradictory material information in an attempt to deceive and mislead the USPTO regarding the patentability of the amended claims.

25. Senju and Kyorin also amended reexamination claim 6 knowing that the added limitations to the claimed methods were not supported by the written description of the '045 patent specification, and thus reexamined claim 6 was invalid.

26. On information and belief, Senju and Kyorin sought reexamination claims 1-3, 6, 8, and 9 despite knowing that these reexamination claims in amended form were invalid as obvious and/or for violating the written description requirement of 35 U.S.C. § 112, ¶1.

27. On information and belief, Senju and Kyorin withheld this material information with an intent to deceive and mislead the USPTO regarding the patentability of the amended and/or added claims.

28. Senju and Kyorin submitted new claims 12-16 in the reexamination to narrow the

scope of the compositions that had been claimed in claims 1-3 and 9, which were canceled.

29. On information and belief, Senju and Kyorin committed inequitable conduct by seeking new claims 12-16 (aqueous liquid compositions comprising gatifloxacin and disodium edetate) which as a matter of law are invalid in light of Senju and Kyorin's and/or their expert's concession in litigation that claim 8 (incorporating disodium edetate into a liquid aqueous gatifloxacin composition for the purpose of preventing coloration) is invalid.

30. Senju and Kyorin made a material omission by failing to disclose the Kyorin's researchers' prior invention of gatifloxacin ophthalmic formulations containing disodium edetate and sodium chloride.

31. On October 25, 2011, the USPTO issued a reexamination certificate determining that amended claim 6 and new claims 12-16 are patentable over the materials submitted by Senju and Kyorin in the reexamination. These claims read as follows:

6. A method for raising corneal permeability of an aqueous pharmaceutical Gatifloxacin eye drop solution comprising Gatifloxacin or its salt, having a pH from above 5 to about 6 containing from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt which comprises incorporating about 0.01 w/v% disodium edetate into [eye drops containing Gatifloxacin or its salt] said Gatifloxacin eye drop solution.

12. An aqueous liquid pharmaceutical eye drop composition which comprises from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt, about 0.01 w/v% disodium edetate, and wherein the aqueous liquid pharmaceutical composition has a pH from about 5 to about 6.

13. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.3 w/v% Gatifloxacin or its salt.

14. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.5 w/v% Gatifloxacin or its salt.

15. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising at least one isotonic agent selected from the group consisting of sodium chloride, potassium chloride, glycerin, mannitol and glucose.

16. The aqueous liquid pharmaceutical eye drop composition according to claim 14, wherein the at least one isotonic agent is sodium chloride.

32. In the Examiner's Statement of Reasons for Patentability and/or Confirmation, the Examiner states that the prior art fails:

to teach or reasonably suggest, alone or in combination...an aqueous liquid pharmaceutical eye drop composition that comprises the claimed amounts of gatifloxacin (from about 0.3 w/v% to about 0.8 w/v% gatifloxacin or its salt) and the incorporation of disodium edetate in the particular amounts that are recited in the claims (about 0.01[sic] w/v% disodium edetate) at a pH from about 5 to about 6 (**claim 12**).

33. The Examiner further suggested that claim 12 was patentable because Senju and Kyorin submitted evidence of a secondary consideration that favored patentability—unexpected results of increased corneal permeability for the claimed compositions, without evidence of other secondary considerations.

34. On information and belief, Senju and Kyorin made these material misrepresentations and omissions with an intent to deceive the USPTO as to the patentability of the reexamined claims.

35. But for Senju's and Kyorin's material misrepresentations and omissions, the USPTO would not have reached these conclusions and the reexamined claims of the '045 patent would not have issued.

36. Senju's and Kyorin's and/or their prosecuting attorneys' material misrepresentations and omissions amounted to affirmative egregious misconduct in dealing with the USPTO.

**PRAYER FOR RELIEF**

**WHEREFORE**, Apotex, Inc. and Apotex Corp, respectfully request the Court to enter judgment against counterclaim defendants Senju, Kyorin, and Allergan as follows:

A. Declaring that Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '045 patent either literally or under the doctrine of equivalents.

B. Declaring that U.S. Patent No. 6,333,045 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, 102, 103, and/or 112.

C. Declaring that U.S. Patent No. 6,333,045 is unenforceable as a result of inequitable conduct and/or unclean hands committed during its reexamination before the USPTO.

D. Declaring that Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '283 patent either literally or under the doctrine of equivalents.

E. Declaring that U.S. Patent No. 5,880,283 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, 102, 103, and/or 112.

F. Awarding Apotex Corp. its reasonable costs and attorneys fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

G. Awarding all such other and further relief as this Court may deem just and proper.

Dated: March 16, 2012

Respectfully Submitted,

MURPHY & LANDON

/s/Francis J. Murphy

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**Attorneys for Defendant  
Apotex Corp.**

**CERTIFICATE OF SERVICE**

The undersigned on oath states that foregoing **DEFENDANTS APOTEX, INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIM TO PLAINTIFF'S COMPLAINT** was served on the following counsel by electronic filing with the Court's ECF system and by placing a true and correct copy in the U.S. Mail on this 16th day of March 2012.

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